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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,834	01/25/2006	Kimoon Kim	1751-396	7491

6449 7590 08/13/2007  
ROTHWELL, FIGG, ERNST & MANBECK, P.C.  
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WASHINGTON, DC 20005

EXAMINER
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SAMALA, JAGADISHWAR RAO

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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08/13/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

## Office Action Summary

**Application No.**

10/565,834

**Applicant(s)**

KIM ET AL.

**Examiner**

Jagadishwar R. Samala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>04/11/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### **Status of Application**

1. Applicant's election of group I in paper filed on June 5, 2007 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse: see MPEP 818.03(a).

Claims 1-7 are pending in the application. Claims 8-12 are withdrawn from further consideration as being directed to non-elected invention.

### **Information Disclosure Statement**

2. The Information Disclosure Statement filed on April 11, 2006 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office Action.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 5-7 are rejected under 35 U.S.C.112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 5 is drawn to the pharmaceutical composition of claim 4, wherein the pharmaceutically active substance is an "organic

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compound, a protein, or a gene". While the examiner acknowledges that the term "organic compound, a protein, a gene" is mentioned in the instant specification, the term is not defined by the instant specification in a clear and concise manner. The specification discloses examples of some organic compounds and proteins within the scope of what is claimed. However these are not considered to be representative species for the side variation of chemical moieties within "organic compounds, proteins or a gene" which may include small organic molecules as well as, large macromolecules, proteins comprising various amino acids, peptides, amino acid sequence and thereof. And further, there is no evidence that there is any per se structure/function relationship between the disclosed protein, gene, and organic compounds and any others that might be found using the claimed composition. Structural identifying characteristics of group of "organic compound, a protein, or a gene" are not disclosed.

There is no sufficient evidence to convey to one of ordinary skill in the art that applicant was in possession of the claimed invention. Therefore, the claimed invention is not supported by an adequate written description.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO-03/055888 A1) in view of Pun et al. (US 2003/0008818 A1).

Kim discloses the preparation of hydroxycucurbituril derivatives as recited in claim 1. And hydroxycucurbituril and their derivatives can include various compounds with different sizes, and have Lewis base atoms near the cavities of the molecule, which can form complex with various organic compounds, and thus the cucurbituril derivatives can have a wide range of applications. And further, cucurbituril derivatives can be used as additives to polymers, cosmetics, drugs and food, and used as drug carriers (see page 17 and 18).

Kim meets the limitations as described above but fails to include biodegradable polymers such as PGLA, PEG, cellulose derivatives, albumin, gelatin, alginate therein.

However, it would have been obvious to one of ordinary skill in the art at the time of invention was made to incorporate additional biodegradable polymers such as PGLA, PEG, cellulose derivatives, albumin, gelatin, alginate to increase the therapeutic efficacy

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when Kim is taken in view of Pun teaches a composition containing particulate composite of a polymer and a therapeutic agent, and the composition can be used to treat carious disorders.

Pun discloses a composition containing particulate composite of a biodegradable polymer (PEG) and a therapeutic agent and a complexing agent, wherein polymer interacts with the complexing agent in a host-guest or a guest-host interaction to form an inclusion complex. And also composition can be used to deliver a therapeutic agent in the treatment of various disorders (see paragraph 0002). And also discloses suitable hosts which may be employed with the polymer include cavitands, crown ethers, cucurbiturils, calixarenes, cryptands and the like (see paragraph 0105), and therapeutic agents such as antibiotics, steroids, polynucleotides, plasmids, peptides, natural products and other biologically active macromolecules such as proteins and enzymes (see paragraph 0110).

When these references are taken together, one would have been motivated to extend Kim's teaching to add additional biodegradable polymers such as PGLA, PEG, cellulose derivatives, albumin, gelatin, alginate to maximize therapeutic efficacy. As suggested by cited references, one would have reasonably expected successful addition of biodegradable polymers because the effectiveness, extra benefits (facilities its clinical use and aid in the diagnosis before and after the treatment and further for the treatment of inherited or acquired disorders such as for e.g. cystic fibrosis, Gaucher's disease, muscular dystrophy, AIDS, cancers and neurological conditions is possible and

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thus the therapeutic effect on said disorders can be enhanced) and safety are already well proven and are well suggested by latter reference cited.

One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extended therapeutic modalities to improve patient's compliance by enhancing patient satisfaction and increasing the selection option. The techniques and skills required for making such substitution is conventional knowledge or well within the skills of ordinary artisan as evidenced by these references cited.

Those of ordinary skill in the art would expect similar benefits from the instant composition of hydroxycucurbituril derivatives used as drug carriers, given the teachings of Kim in view of Pun. One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01 (a).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Zohreh Fay  
Primary Examiner  
Group 1600

Jagadishwar R Samala  
Examiner  
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